## **SAFETY DATA SHEETS**

## This SDS packet was issued with item:

071718741

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071718659 071718691 071718907 071718915 071718923

## Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard, 25 CFR 1910.1200. Standard must be consulted for specific requirements.

## U.S. Department of Labor

Occupational Safety and Health Administration (Non-Mandatory Form) Form Approved OMB No. 1218–0072



IDENTITY (As Used on Label and List) Dycal Base		Note: Blank spaces are not permitted, if any item is not applicable, or no information is available, the space must be marked to indicate that.			
Section I					
Manufacturer's Name  Caulk/Pentsply  Address (Number, Street, City, State, and ZIP Code)  Lakeview C. Clarke Avenues  Milford, DE 19963-0359		(302) // Teleonone Nun (302) Date Prepared 1/13/3			
Section II — Hazardous Ingredie	nts/Identity Information	1			
Hazardous Components (Specific Chemical	I Identity: Common Name(s))	OSHA PEL	ACGIH TLV	Other Limits Recommended	% (optional
Zinc Oxide			5 mg/m <sup>3</sup> TWA		
Section III — Physical/Chemical Boiling Point		Specific Gravity	/ (H <sub>2</sub> O = 1)		
Vapor Pressure (mm Hg.)	N.A.	Melting Point			1.98
Vapor Fressure (mm Fig.)	N.A.				N.E.
Vapor Density (AIR = 1)	N.A.	Evaporation Ra (Butyl Acetate			N.A.
Solubility in Water Not soluble					
Appearance and Odor Tan paste with charac		wintergree	en		
Section IV — Fire and Explosion	1 Hazard Data	15		T. 21 T	1151
Flash Point (Method Used) N.A.		Flammable Lin	N.A.	Y.A.	UEL
Extinguishing Media Carbon dioxide, Halon Special Fire Fighting Procedures None Unusual Fire and Explosion Hazards	1 -				
None					

(Reproduce locally)

OSHA 174, Sept. 1985

N.A. Data does not apply to this product.

N.E. Value has not been established for this product.

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

Section V	Reactivity Data			
Stability	Unstable		Conditions to Avoid	
	Stable	х	None	
Incompatibility (	(Materials to Avoid)	_ <u> </u>	HOLLE	
Not	ne			
Hazardous Deco	mposition or Byprodu	CTS		
Hazardous Polymenzation	May Occur		Conditions to Avoid	
,	Will Not Occur	Х	None	
Section VI -	- Health Hazard	ــــــــــــــــــــــــــــــــــــــ		
Route(s) of Entry		авол?	Skin?	Ingestion?
Health Hazards /	(Acute and Chronic)	o rsk	Yes in irritation (redness). Av	Possibly oid prolonged or repeated
sk:	in contact.			
Carcinogenicity:	NTP No		IARC Monographs?	OSHA Regulated?
Signs and Symp	noms of Exposure Minor sk	in 1	rritation (redness)	
Medical Conditio				
	veted by Exposure			· · · · · · · · · · · · · · · · · · ·
	in irritatio			
Emergency and √a:	sh thoroughl	y wi	th soap and water if prolon	ged contact is made.
			ists please consult a physi	
Section VII -	- Precautions fo	or Sa	e Handling and Use	
	en in Case Material I		<u>~</u>	
Wi	<u>pe up with c</u>	lean	cloth or paper towel. Scru	b area with alcohol.
_				
Waste Disposal	Method proved landf	411		
	brosed raudi	<u> </u>	<del></del>	
Precautions to B	Se Taken in Handling	and S	nring.	
Ste	ore at room	cemp	erature. Avoid storage abov	re 50°C (122°F)
Other Precaunor				
No	ne			<del></del>
	<del></del>			
	- Control Meas	ures		
	ection (Specify Type) cal exhaust			
Ventilation	Local Exhaust Yes		Special	
Local	Yes Mechanical (General		Other	N.A.
exhaust	Nechanica (General N. A	•		11. A.
Protective Glove	_		Eye Protection	
	bber gloves Clothing or Equipme	nt		Shield
Ra	bber apron		<del></del>	
Work/Hygienic F	ractices hands with	soar	and water. Avoid excessive	contact with skin.
			Page 2	# USGPO. 1986-491-529/45775

N.A. Data does not apply to this product.

N.E. Value has not been established for this product.

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Dycal Base

· Application: Base paste

- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Material for pulp capping
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier: DENTSPLY DeTrey GmbH

De-Trey-Str. 1 D-78467 Konstanz

GERMANY

*Tel.*: +49-(0)7531-583-0 *Fax*: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- $\cdot$  1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation. Eye Irrit. 2 H319 Causes serious eye irritation.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms





GHS07

GHS09

- · Signal word Warning
- · Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

*P273* Avoid release to the environment.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

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- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable. · **vPvB**: Not applicable.

### SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:			
CAS: 73240-13-8	1,3- Butylenglykoldisalicylat	25-50%	
	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319		
	Q	2.5-10%	
EINECS: 215-222-5	🔖 Aquatic Acute 1, H400; Aquatic Chronic 1, H410		

· Additional information For the wording of the listed risk phrases refer to section 16.

## **SECTION 4:** First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

#### SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · 6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling

 $See \ Section \ 8 \ for \ information \ on \ personal \ protection \ equipment.$ 

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See Section 13 for disposal information.

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### **SECTION 7: Handling and storage**

### · 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Observe normal care for working with chemicals.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- ·Storage
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep receptacle tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

#### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

#### · Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· Eye protection:





Tightly sealed goggles.

 $\cdot \textit{Body protection:} \ \textit{Protective work clothing.}$ 

9.1 Information on basic physical of	and chemical properties
General Information Appearance:	
Form:	Pasty
Colour:	Dark
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable
Flammability (solid, gaseous)	Not applicable.
Ignition temperature:	Not applicable
Decomposition temperature:	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density at 20 °C:	$1.98 \ g/cm^3$
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content:	
Organic solvents:	0.0 %

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## SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

## **SECTION 11: Toxicological information**

- · 11.1 Information on toxicological effects
- · Acute toxicity
- · LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 6452 mg/kg

#### 1314-13-2 zinc oxide

*Oral* | *LD50* | >5000 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- $\cdot \textit{CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)}\\$
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- $\cdot \textit{Carcinogenicity Based on available data, the classification criteria\ are\ not\ met.}$
- $\cdot \textit{Reproductive toxicity Based on available data, the classification criteria are not met.}$
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity:

1314-13-2 zinc oxide

EC50/48h 0.098 mg/L (daphnia magna)

LC50/96h 1.1 mg/l (Fish acute toxicity study)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.

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# Safety data sheet according to 1907/2006/EC, Article 31

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R. Not applicable

· vPvB: Not applicable.

 $\cdot \ \textbf{12.6 Other adverse effects} \ \textit{No further relevant information available}.$ 

## SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06\* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- $\cdot \textit{Recommendation:} \ \textit{Disposal must be made according to official regulations.}$

SECTION 14: Transport informa	ation
· 14.1 UN-Number · ADR, IMDG, IATA	UN3082
· 14.2 UN proper shipping name · ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANC. LIQUID, N.O.S. (zinc oxide)
· IMDG · IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE
14.2 Transmort hazard alass(cs)	LIQUID, N.O.S. (zinc oxide)
· 14.3 Transport hazard class(es) · ADR	
· Class	9 (M6) Miscellaneous dangerous substances and articles. 9
IMDG, IATA	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substance zinc oxide
· Marine pollutant:	Yes Symbol (fish and tree)
Special marking (ADR):	Symbol (fish and tree)

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	(Contd. of page	
Special marking (IATA):	Symbol (fish and tree)	
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.	
Danger code (Kemler):	90	
EMS Number:	F- $A$ , $S$ - $F$	
14.7 Transport in bulk according to Ann	ex II of	
Marpol and the IBC Code	Not applicable.	
Transport/Additional information:		
ADR		
Limited quantities (LQ)	5L	
Excepted quantities $(EQ)$	Code: El	
	Maximum net quantity per inner packaging: 30 ml	
	Maximum net quantity per outer packaging: 1000 ml	
Transport category	3	
Tunnel restriction code	E	
Remarks:	Exemption according to ADR special provision 375:	
	This substance is not subject to the other provisions of th	
	ADR if packed in net quantities of 5L or 5kg per individua	
	or inner packaging, provided that sub-sections 4.1.1.1	
	4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with.	
<i>IMDG</i>		
Limited quantities (LQ)	5L	
Excepted quantities (EQ)	Code: E1	
	Maximum net quantity per inner packaging: 30 ml	
	Maximum net quantity per outer packaging: 1000 ml	
UN ''Model Regulation'':	UN3082, ENVIRONMENTALLY HAZARDOU	
	SUBSTANCE, LIQUID, N.O.S. (zinc oxide), 9, III	

## **SECTION 15: Regulatory information**

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

#### · Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · Department issuing MSDS: Analytical Research
- · Contact: HotLine for urgent technical support: +49-7531-583-350
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

\* \* Data compared to the previous version altered.

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